510(K) Summary of Safety and Effectiveness
AMSure® Nebulizer

Company: Amsino International, Inc.
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Pomona, CA 91767
(909) 626-5888
Contact: Ching Ching Seah, Ph.D.
Director of Regulatory Affairs

OCT 1 ~ 2007

Date Prepared: August 8, 2007

Classification Name: Nebulizer (Direct Patient Interface) (868.5630)
Common Name: Nebulizer
Proprietary Name: *AMSure*® Nebulizer
Product Code: CAF
Medical Specialty: Anesthesiology
Device Class: Class II

Predicate Devices: **Hudson RCI Micro Mist®** (K930525)

Device Description: The *AMSure*® Nebulizer is a single-use patient device, which is filled with fluid, typically respiratory medication and connected to a source of compressed via flexible tubing. The nebulizer delivers aerosolized fluids for patient inhalation in the respirable range of approximately 1.0μm to 5.0μm. It operates on a compressed gas source which draws liquids from a refillable cup by the Venturi Principle and aerosolizes it by impaction and baffling.

Intended Use: The ***AMSURE***® Nebulizer is intended for the administration of various aerosol treatments in both the homecare and hospital settings. This device is intended for use only with FDA-approved drugs for nebulization, under the direction of a physician. It can be used for both pediatric and adult patient populations.

Comparison to Predicate: The ***AMSure***® Nebulizer is similar to the predicate devices in operational principle, materials, design, technical characteristics and intended use. Any differences do not affect the intended use or the safety and effectiveness of the device.

Non-Clinical Testing: Performance and biocompatibility testing has demonstrated that the ***AMSure***® Nebulizer is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ching Ching Seah, Ph.D.
Director of Research, Development and Regulatory Affairs
Amsino International, Incorporated
855 Towne Center Drive
Pomona, California 91767

OCT 1 ˇ 2007

Re: K070411
Trade/Device Name: AMSURE® Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: September 19, 2007
Received: September 24, 2007

Dear Dr. Seah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: (if known)	**K070411**
Device Name:	***AMSURE***® Nebulizer
Indications for Use:	The ***AMSURE***® Nebulizer is intended for the administration of various aerosol treatments in both the homecare and hospital settings. This device is intended for use only with FDA-approved drugs for nebulization, under the direction of a physician. It can be used for both pediatric and adult patient populations.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801. 109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

(Division Sign-Off)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070411